(b) The following Hawaii medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them exemption from preemption: Hawaii Revised Statutes, chapter 451A, §14.1, subsection (a) to the extent that it requires a written authorization by a physician and does not allow adults to waive this requirement for personal, as well as religious reasons, and subsection (b).

[50 FR 30699, July 29, 1985; 50 FR 32694, Aug. 14, 1985]

§ 808.67 Kentucky.

The following Kentucky medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Kentucky Revised Statutes, section 334.200(1).

[45 FR 67336, Oct. 10, 1980]

§ 808.69 Maine.

(a) The following Maine medical device requirement is enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted it from preemption under section 521(b) of the act: Maine Revised Statutes Annotated, Title 32, section 1658–C, on the condition that, in enforcing this requirement, Maine apply the definition of ''used hearing aid'' in §801.420(a)(6) of this chapter.

(b) The following Maine medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Maine Revised Statutes Annotated, Title 32, section 1658–D and the last sentence of section 1658–E.

[45 FR 67336, Oct. 10, 1980]

§ 808.71 Massachusetts.

(a) The following Massachusetts medical device requirements are enforceable notwithstanding section 521 of the act because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act:

(1) Massachusetts General Laws, Chapter 93, Section 72, to the extent that it requires a hearing test evaluation for a child under the age of 18.

(2) Massachusetts General Laws, Chapter 93, Section 74, except as provided in paragraph (6) of the Section, on the condition that, in enforcing this requirement, Massachusetts apply the definition of ''used hearing aid'' in §801.420(a)(6) of this chapter.

(b) The following Massachusetts medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them exemptions from preemption under section 521(b) of the act.

(1) Massachusetts General Laws, Chapter 93, Section 72, except as provided in paragraph (a) of this section.

(2) Massachusetts General Laws, Chapter 93, Section 74, to the extent that it requires that the sales receipt contain a statement that State law requires a medical examination and a hearing test evaluation before the sale of a hearing aid.

[45 FR 67326, Oct. 10, 1980]

§ 808.73 Minnesota.

The following Minnesota medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them an exemption from preemption under section 521(b) of the act: Minnesota Statutes, sections 145.43 and 145.44.

[45 FR 67336, Oct. 10, 1980]

§ 808.74 Mississippi.

The following Mississippi medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Mississippi Code, section 73–14–3(g)(9).

[45 FR 67336, Oct. 10, 1980]

§ 808.77 Nebraska.

(a) The following Nebraska medical device requirement is enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted it from preemption under section 521(b) of the act: Nebraska Revised Statutes, section 71–4712(2)(c)(vi).

(b) The following Nebraska medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Nebraska Revised Statutes, section 71–4712(2)(c)(vii).

[45 FR 67336, Oct. 10, 1980]

§ 808.80 New Jersey.

(a) The following New Jersey medical device requirements are enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act:

(1) New Jersey Statutes Annotated, section 45:9A–23 on the condition that, in enforcing this requirement, New Jersey apply the definition of ''used hearing aid'' in § 801.420(a)(6) of this chapter;

(2) New Jersey Statutes Annotated, sections 45:9A–24 and 45:9A–25;

(3) Chapter 3, Section 5 of the Rules and Regulations adopted pursuant to New Jersey Statutes Annotated 45:9A–1 et seq. except as provided in paragraph (b) of this section.

(b) The following New Jersey medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Chapter 3, Section 5 of the Rules and Regulations adopted pursuant to New Jersey Statutes Annotated 45:9A–1 et seq. to the extent that it requires testing to be conducted in an environment which meets or exceeds the American National Standards Institute S3.1 Standard.

[45 FR 67337, Oct. 10, 1980]

§ 808.81 New Mexico.

The following New Mexico medical device requirement is enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted it from preemption under section 521(b) of the act: New Mexico Statutes Annotated, section 67–36–16(F).

[45 FR 67337, Oct. 10, 1980]

§ 808.82 New York.

(a) The following New York medical device requirements are enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act:

(1) General Business Law, Article 37, sections 784(3) and (4).

(2) Official Compilation of Codes, Rules and Regulations of the State of New York, Chapter V, Title 19, Subchapter G, section 191.10 and section 191.11(a) on the condition that, in enforcing these requirements, New York apply the definition of ''used hearing aid'' in § 801.420(a)(6) of this chapter and section 191.11(b), (c), (d), and (e).

(b) The following New York medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them an exemptions from preemption under section 521(b) of the act:

(1) General Business Law, Article 37, section 784.1.

(2) Official Compilation of Codes, Rules and Regulations of the State of New York, Chapter V, Title 19, Subchapter G, sections 191.6, 191.7, 191.8, and 191.9.

[45 FR 67337, Oct. 10, 1980]

§ 808.85 Ohio.

(a) The following Ohio medical device requirement is enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted it from preemption under section 521(b) of the act: Ohio Revised Code, section 4747.09, the first two sentences with respect to disclosure of information to purchasers on the condition that, in enforcing these requirements, Ohio apply the definition of ''used hearing aid'' in § 801.420(a)(6) of this chapter.

(b) The following Ohio medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Ohio Revised Code, section 4747.09, the last two sentences with respect to medical examination of children.

[45 FR 67337, Oct. 10, 1980]

§ 808.87 Oregon.

(a) The following Oregon medical device requriements are enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act: Oregon Revised Statutes, section 694.036 on the condition that, in enforcing this requirement, Oregon apply the definition of ''used hearing aid'' in § 801.420(a)(6) of this chapter.

(b) The following Oregon medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them exemptions from preemption under section 521(b) of the act: Oregon Revised Statutes, sections 694.136(6) and (7).

[45 FR 67337, Oct. 10, 1980, as amended at 53 FR 11252, Apr. 6, 1988]

§ 808.88 Pennsylvania.

(a) The following Pennsylvania medical device requirements are enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act: 35 Purdon's Statutes 6700, section 504(4) on the condition that, in enforcing this requirement, Pennsylvania apply the definition of ''used hearing aid'' in § 801.420(a)(6) of this chapter; section 506; and, section 507(2).

(b) The following Pennsylvania medical device requirement is preempted by section 521(a) of the act and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: 35 Purdon's Statutes 6700, section 402.

[45 FR 67326, Oct. 10, 1980]

§ 808.89 Rhode Island.

The following Rhode Island medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them an exemption from preemption under section 521(b) of the act: Rhode Island General Laws, Section 5–49–2.1, and Section 2.2, to the extent that Section 2.2 requires hearing aid dispensers to keep copies of the certificates of need.

[45 FR 67337, Oct. 10, 1980]

§ 808.93 Texas.

(a) The following Texas medical device requirement is enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted it from preemption under section 521(b) of the act: Vernon's Civil Statutes, Article 4566, section 14(b) on the condition that, in enforcing this requirement, Texas apply the definition of ''used hearing aid'' in § 801.420(a)(6) of this chapter.

(b) The following Texas medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Vernon's Civil Statutes, Article 4566, section 14(d).

[45 FR 67337, Oct. 10, 1980]

§ 808.97 Washington.

(a) The following Washington medical device requirement is enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted it from preemption under section 521(b) of the act: Revised Code of Washington 18.35.110(2)(e)(i) and (iii) on the condition that it is enforced in addition to the applicable requirements of this chapter.

(b) The following Washington medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them an exemption from preemption under section 521(b) of the act: Revised Code of Washington 18.35.110(2)(e)(ii).

[45 FR 67337, Oct. 10, 1980]

§ 808.98 West Virginia.

(a) The following West Virginia medical device requirements are enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted them from preemption: West Virginia Code, sections 30–26–14 (b) and (c) and section 30–26–15(a) on the condition that in enforcing section 30–26–15(a) West Virginia apply the definition of ''used hearing aid'' in § 801.420(a)(6) of this chapter.